

REMARKS

Claims 1-19 were examined. Claim 16 is amended. Claims 1-19 remain in the application.

The Patent Office rejects claims 1 and 13 under 35 U.S.C. §102(b). The Patent Office rejects claims 2-12 and 14-19 under 35 U.S.C. §103(a). Reconsideration of the rejected claims is respectfully requested in view of the above amendments and the following remarks.

A. 35 U.S.C. §102(b): Rejection of Claims 1 & 13

The Patent Office rejects claims 1 and 13 under 35 U.S.C. §102(b) in view of U.S. Patent No. 4,535,773 of Yoon (Yoon). The Patent Office cites Figures 34 and 35 which disclose a two-part, internally retractable puncturing implement 472. The implement as a shaft with a greater diameter section 44 at its distal end terminating in a sharp, multi-sided blade 46 and point 48 bearing one or more pressure sensors or transducer elements 442. The intermediate section of shaft 42 is able to slide within a hollow proximal tubular section 474. Coiled tension springs 476 as opposite ends attached to proximal ends 477 of intermediate shaft section 42 and threaded plug 478 is proximal end 480 of tubular section 474. Intermediate shaft section 42 contains detent mechanism 486 holding a small detent 488 urged radially outward by compression spring 490. When intermediate shaft section 42 is fully extended axially outward from tubular section 474, detent 488 is co-axially aligned with and protrudes through hole 492 in the wall of the tubular section. Electrical leads 444 pass through the interior of distal and intermediate sections 44, 42 and are coupled to plate sensors 442 to electrical contacts within detent 488. Electrical leads 464 pass along instrument sleeve 12 couple pressure sensors 462 fitted into a distal end of the sleeve with electrical socket 90. See col. 17, lines 5-32.

Prior to use, the distal and intermediate sections of implements 472 are pulled axially outward from the tubular section until detent 488 engages and passes through the detent hole 492. Handle assembly 352 is then attached to proximal end 480 of the tubular section and distal end 44 of the implement are inserted through a gate valve and sleeve 11 of the instrument. Col.

17, lines 36-40. When fully inserted into the sleeve, detent 488 is co-axially aligned with radial solenoid socket 494 adjacent electrical socket 90. Col. 17, lines 40-42. Electrical plug assembly 496 contains an electrical jack to couple sleeve sensors 462 to an expanded alarm network and solenoid 498 having electrical contacts to couple blade sensors 442 via leads 444 and the contacts carried by detent 488 through solenoid socket 494 to the alarm network in parallel with the sleeve sensors.

When the blade 46 of the implement is pressed against a cavity wall, the counterforce exerted by the skin, tissues and membranes on the pressure sensors 442 in the blade trigger the alarm network with a sequential set of ready signals. Counterforce subsequently exerted on the sleeve sensors 462 which provides the alarm network with a second signal may be used to verify this indication. Disappearance of the counterforce against the blade sensors 442 as the blade passes into the cavity interior provides the alarm network with a sequential set of signals which may be used as an indication of the near completion of the puncture. . . . Energization of the solenoid [in response to the set of signals] causes its plunger to depress detent 498, thereby releasing the intermediate shaft section 42 and permitting tension spring 476 to retract the intermediate and distal sections 42, 44 of the implement towards the proximal end 489 of the implement. This action effectively causes the spring 476 to withdraw the implement blade 46 and point 48 within the instrument sleeve 11, shielding the anatomical structure within the cavity for inadvertent contact with the blade. Subsequent disappearance of counterforce against the sleeve sensors 462 as the distal end 15 of the sleeve passes into the cavity interior provides the alarm network with a fourth signal which indicates completion of the puncture.

Col. 17, line 51 through col. 18, line 13. As described, Yoon uses tension spring 476 to retract intermediate and distal sections 42 and 44 of the implement in response to an alarm once a blade has been inserted through a cavity wall. In other words, the intermediate and distal sections 42 and 44 of the device described in Figures 34 and 35 of Yoon do not move in response to a resistive force but instead after a resistive force has disappeared.

Independent claim 1 describes an apparatus including a needle and a device coupled to the needle including a conductive component adapted to move in response to a resistive force, wherein a movement corresponds to depth of tissue penetration. Claim 1 is not anticipated by Yoon, because Yoon does not disclose a device coupled to a needle comprising a conductive component adapted to move in response to a resistive force wherein a move corresponds to a depth of tissue penetration. As noted above, intermediate and distal sections 42, 44 of Yoon move in response to the disappearance of a counterforce against a needle, not in response to a resistive force.

Independent claim 13 provides an apparatus including a spring loaded needle, a first conductive element coupled to the needle and slidably movable upon contact with and penetration into a tissue wall, and a second conductive element disposed at a predetermined distance from the first conductive element, the second conductive element arranged to generate an electrical signal upon contact with the first conductive element. Claim 13 is not anticipated by Yoon, because Yoon does not disclose a first conductive element slidably movable upon contact with and penetration into a tissue wall. As noted above, intermediate and distal sections 42, 44 of Yoon move in response to disappearance of a counterforce.

Applicant respectfully requests the Patent Office withdraw the rejection to claims 1 and 13 under 35 U.S.C. §102(b) over Yoon.

B. 35 U.S.C. §103: Rejection of Claims 2-12 & 14-19

The Patent Office rejects claims 2-12 and 14-19 under 35 U.S.C. §103(a) as obvious over Yoon in view of U.S. Patent No. 5,893,848 of Negus et al. (Negus); U.S. Patent No. 6,391,005 of Lum et al. (Lum); U.S. Patent No. 6,024,703 of Zanelli et al. (Zanelli); U.S. Patent No. 6,706,015 of Cory et al. (Cory); and U.S. Patent No. 6,569,144 of Altman (Altman). The Office Action does not make clear which elements of the depending claims are taught by any or all of the cited references. Yoon is cited for its teachings with respect to claims 1 and 13.

Claims 2-12 depend from claim 1 and therefore contain all the limitations of that claim. Claims 2-12 are prima facie not obvious over the cited references, because the references fail to describe an apparatus including a needle and a device coupled to the needle including a conductive component adapted to move in response to a resistive force wherein a movement corresponds to a depth of tissue penetration. As Yoon is relied on for this teaching, the arguments presented above regarding Yoon have been discussed. Combining Yoon with the other references does not cure this deficiency. Applicant also notes that no argument is presented why claims 2-5 or 10-12 are obvious over the cited references.

With respect to elements of a spring-machine assembly, weld joint, and a slip-fit joint (e.g., claims 6-9), the Patent Office characterizes these terms as product-by-process claims. Applicant respectfully submits that elements set forth in these claims further define the structure of the apparatus of, for example, claim 1 and present structural limitations of the apparatus. Applicant disagrees with the characterization of a process limitation.

Claims 14-15 depend from claim 13 and therefore contain all the limitations of that claim. Claims 14-15 are not obvious over the cited references because the cited references fail to teach an apparatus including a needle and a first conductive element coupled to the needle and slidably movable upon contact with and penetration into a tissue wall, and a second conductive element to generate an electrical signal upon contact with the first conductive element. In this regard, the arguments presented above regarding Yoon (the primary reference) are relevant here. The combination of Yoon with the other references does not cure the defects in Yoon. Applicant also notes that no argument is presented by the Patent Office as to why claims 14 and 15 are obvious.

Independent claim 16 describes a method including penetrating a tissue wall with a needle assembly, the needle assembly comprising a needle, a first conductive element coupled to the needle, and a second conductive element disposed at a predetermined distance away from the first conductive element. A resistive force in response to the penetration allows the first conductive

element to slidably move toward the second conductive element. The method further includes delivering an appropriate treatment agent through the needle assembly.

Claim 16 is not obvious over the cited references, because the cited references do not describe a method including penetrating a tissue wall with a needle assembly wherein a resistive force in response to the penetration allows a first conductive element of the needle assembly to slidably move toward a second conductive element. Yoon is cited for this teaching. As described above, however, Yoon teaches retraction of intermediate and distal sections 42, 44 of its puncturing instruments upon disappearance of a counterforce. The additional references cited by the Patent Office in the §103 rejection do not cure the deficiency of Yoon.

Claims 17-19 depend from claim 16 and therefore contain all the limitations of that claim. For the reasons stated with respect to claim 16, claims 17-19 are not obvious over the cited references. It is noted that no explanation of obviousness is presented by the Patent Office with respect to these claims.

For the above stated reasons, Applicant respectfully requests that the Patent Office withdraw the rejection to claims 2-12 and 14-19 under 35 U.S.C. §103(a).

CONCLUSION

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record and are in condition for allowance and such action is earnestly solicited at the earliest possible date.

Respectfully submitted,

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Dated: _____

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I hereby certify that this correspondence is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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